Health Information Technology Advisory Committee

Pharmacy Interoperability and Emerging Therapeutics Task Force 2023 Virtual Meeting

Meeting Notes | July 12, 2023, 10:30 AM – 12 PM ET

Executive Summary

The goal of the Pharmacy Interoperability and Emerging Therapeutics (PhIET) Task Force meeting on July 12 was to continue discussion on Short-Term and Long-Term Public Health, Emergency Use Authorizations, and Prescribing Authorities. Tegan Boehmer, US Public Health Service Acting Chief, Actionable Data Branch, Inform and Disseminate Division, Office of Public Health, Data, Surveillance, and Technology attended the meeting for a Q&A session on Public Health Surveillance and Insights from Therapeutics Data: The COVID-19 Experience, and a robust discussion followed.

Agenda

10:30 AM	Call to Order/Roll Call
10:35 AM	Opening Remarks
10:40 AM	Task 1 Short Term Recommendation for Public Health, Emergency Use Authorizations, and Prescribing Authorities
11:10 AM	Guest Presentation and Question and Answer
11:30 AM	Task 1 Long Term Recommendation for Public Health, Emergency Use Authorizations, and Prescribing Authorities
11:50 AM	Public Comment
11:55 AM	Task Force Work Planning
12:00 PM	Adjourn

Call to Order

Mike Berry, Designated Federal Officer, Office of the National Coordinator for Health IT (ONC), called the meeting to order at 10:32 AM.

Roll Call

Members in Attendance

Hans Buitendijk, Oracle Health, Co-Chair
Shelly Spiro, Pharmacy Health Information Technology Collaborative, Co-Chair
Pooja Babbrah, Point-of-Care Partners
Chris Blackley, Prescryptive
David Butler, Curatro, LLC
Steven Eichner, Texas Department of State Health Services
Jim Jirjis, HCA Healthcare
Adi Gundlapalli, Centers for Disease Control and Prevention (CDC)
Summerpal (Summer) Kahlon, Rocket Health Care

Steven Lane, Health Gorilla
Deven McGraw, Invitae Corporation
Justin Neal, Noble Health Services
Eliel Oliveira, Dell Medical School, University of Texas at Austin
Naresh Sundar Rajan, CyncHealth
Scott Robertson, Bear Health Tech Consulting
Fillipe (Fil) Southerland, Yardi Systems, Inc.
Alexis Synder, Individual
Sheryl Turney, Elevance Health
Afton Wagner, Walgreens

Members Not in Attendance

Shila Blend, North Dakota Health Information Network
Rajesh Godavarthi, MCG Health, part of the Hearst Health Network
Meg Marshall, Department of Veterans Health Affairs
Anna McCollister, Individual
Ketan Mehta, Micro Merchant Systems
Christian Tadrus, Community Pharmacy Owner

ONC Staff

Mike Berry, Designated Federal Officer, ONC
Tricia Lee Rolle, ONC

Key Points of Discussion

Opening Remarks

PhIET Task Force Co-Chairs, Hans Buitendijk and Shelly Spiro, welcomed the Task Force, reviewed the Meeting Agenda, and recapped the Charge. PhIET Task Force recommendations are due to ONC on November 9, 2023.

Task 1 Short Term Recommendation for Public Health, Emergency Use Authorizations, and Prescribing Authorities

Hans Buitendijk reviewed the PhIET Task Force's Recommendation spreadsheet. The Task Force did not provide final recommendations at the July 12 meeting. The recommendations from this meeting were draft recommendations.

Discussion:

- Summer Kahlon noted there is an issue of data communication within the pharmacy industry, specifically with inventory.
    - Hans said some of the recommendations have touched on that. There has been discussion around inventory, and it will continue to be a key theme throughout the Task Force meetings.
- Steven Eichner said another challenge with messaging is finding the "source of truth" for a particular patient. If multiple sources of data are being examined, how does the care team note what is the truth for that patient?
    - Hans noted that is an important point, and it will be further discussed in future Task Force

meeting “themes”.

- Jim Jirjis said there are various “truths” for a patient. Immunization status and prescription “sources of truth” will be found in different places.
    - Steven Eichner agreed there may be different “sources of truth” depending on the situation.
- Pooja Babbrah noted the National Council for Prescription Drug Programs (NCDPD) has standards around inventory. They should be looped into this conversation if it goes deeper.
- Hans asked the Task Force if the current draft recommendations under the “Standards and Data Exchange” section of the Recommendations spreadsheet are comprehensive. Task Force members are welcome to add to the spreadsheet after the meeting.
    - Steven Lane said the recommendation on certification is a long-term opportunity and not something that could be done quickly. Certification programs are one approach to standards and data exchange. There are currently certifications for electronic health records (EHRs), and that is something that could be leveraged in the meantime.
- Steven Eichner agreed with Steven Lane. He noted interface certifications could also be leveraged while new certification programs are developed.
- Jim asked for clarification on if there is a recommendation to start a new certification program.
    - Hans said yes, that is what he is hearing.
- Fil Southerland suggested cross-referencing HTI-1 Proposed Rule recommendations in this spreadsheet. He suggested United States Core Data for Interoperability+ (USCDI+) could play a part in the pharmacy data exchange.
- Shelly Spiro said specialty in pharmacy means something different than in other parts of the healthcare ecosystem. This should be clarified in the recommendations.
- Summer reviewed his recommendation that ensures direct communication to provide real-time communication.
    - Tricia Lee Rolle said inventory is within scope.
- Jim said he will add the availability of pharmaceuticals and ordering signals to inform surveillance into the Recommendations spreadsheet. He noted this could be a short-term recommendation.
- Hans reviewed the Pharmacist Data Capture section of the Recommendations spreadsheet.
    - Afton Wagner said data standards will be important to list as a recommendation. She will work on entering it into the spreadsheet.
    - Pooja said the Task Force should list eCare Plan data capture in the recommendation.

Guest Presentation and Question and Answer

Tegan Boehmer, US Public Health Service Acting Chief, Actionable Data Branch, Inform and Disseminate Division, Office of Public Health, Data, Surveillance, and Technology gave a presentation on Public Health Surveillance and Insights from Therapeutics Data: The COVID-19 Experience. She reviewed Source 1: COVID-19 Therapeutics, National Patient-Centered Clinical Research Network (PCORnet) EHR Data, the Capture of Outpatient COVID-19 Therapeutics and Demographics, and EHR Data Validity and Opportunities. She also reviewed Source 2: HHS Ordering and Dispensing Data and Source 3: Pharmacy Claims Data. Tegan concluded the presentation by reviewing potential opportunities to guide future directions.

Discussion:

- Shelly Spiro suggested the Long-Term Post-Acute Care Model be included in future considerations.
- Steven Lane asked about data collection in antivirals with medications patients were taking at the same time.
    - Tegan Boehmer said it was not looked at specifically. She noted it would be possible to include it in future studies.
- Hans noted claims data is not always sufficient. He asked if enhancing claims is the best approach or if there are other options to make data available.

    - Tegan said that goes outside her scope. She agreed there are limitations to claims data.
- Shelly said there was a similar problem with the prescription drug monitoring (PDM) data. There are other ways to export data other than claims data.
    - Adi Gundlapalli noted it will be a fine balance between timeliness and completeness. Prescriptions are not always filled in a timely manner.

Task 1 Long Term Recommendation for Public Health, Emergency Use Authorizations, and Prescribing Authorities

Hans Buitendijk led the open discussion on Long Term Recommendations.

Discussion:

- Shelly Spiro noted it is important to examine the data elements the CDC is interested in, including the clinical data capture. She added pharmacies have access to lots of data. There should be regulations on what data points need to be collected and how data fields can be expanded through the regulatory process.
- Pooja Babbrah added there is a lot of discussion focused on traditional EHRs. She said it would be beneficial to bring in folks to help showcase various functionalities so the Task Force can draft well-informed recommendations.
- Steven Eichner said it would also be beneficial to bring in public health experts to conduct a presentation on electronic lab reports and electronic case reporting because there are key differences between the two.

PUBLIC COMMENT

Mike Berry, Designated Federal Officer, ONC, opened the meeting up for public comment.

QUESTIONS AND COMMENTS RECEIVED VERBALLY

- Kim Boyd suggested that ONC learn from the EHR certification process and consider how the pharmacy ecosystem can be integrated and not siloed.

QUESTIONS AND COMMENTS RECEIVED VIA ZOOM WEBINAR CHAT

Mike Berry (ONC): Welcome to the Pharmacy Interoperability and Emerging Therapeutics Task Force! Please remember to tag "Everyone" when using Zoom chat. Thank you!

Anthony Master: In one of the forums I'm on with other Interoperability experts, one of them went on a small rant about getting a Rx and then his pharmacy not having the drug and told him to call around himself to see who else might have it available. The customer may not be able to call around with not having the time or resources to do this. Being an interoperability expert, he stated, why don't we have a system that helps with interoperability between pharmacies like this to some extend? I imagine that chains themselves can do this within their own chain, CVS, Walgreens, Walmart, etc. but what about more local and between other pharmacies. We cam up with a proposition, but before the proposition first the assumptions.

The solution need not share PII/PHI. The solution need not share pricing as Pharmacies may not want ot make their prices readily availabiel. The solution should be opt-in with the return on investment being portential customer acquisition for the Pharmacy....

Anthony Master: #2 … Pharmacies probably don't want to send their whole inventory to the Cloud somewhere and keep it updated. When answering a request, only the minimal information needed is "yes" able to meet a request, or "no" not able to meet the request. Pharmacies do not need to disclose the complete quantity on hand. The solution should literally be a more automated workflow than the current one in play (having a customer call around). The solution should not need to store inventory information long-term to keep it affordable and manageable.. Now for the solution:

Heidi Polek: @Anthony Master-I agree that we need to come up with a better way to help patients find the medications they need if the first pharmacy doesn't have it, but pharmacies don't want to lose scripts and I don't see any wanting to participate in a shared data base on in-stock inventory status

Alexis Snyder: Also important is what pharmacy does with that information to get med filled for patient if not available

Summerpal Kahlon: Agree, I don't know that it's feasible to create a real-time, all-pharmacy inventory in the cloud. It seems what we're all really trying to get to is a more efficient way to communicate availability of certain items without an efficient communication system to do so

Justin Neal: Apologies, Justin here joining a little late.

Catherine Graeff: For locating stock in a specific community, I believe a NCPDP task group has been working on a message between pharmacies on this issue of finding stock. Pharmacy A tells patient no stock and asked patient if okay to request electronically. Will result in patient travel to other pharmacy, so need patient okay before. I don't know the status of the message development but can be checked.

Summerpal Kahlon: In large integrated systems, like the VA, this is solved by system-wide Teams chat, so colleagues can ask each other about availability. Outside integrated systems, I think what you're experiencing is more the norm - phone calls are the only way to communicate and sort it out, but that process is time-consuming and inefficient

Alexis Snyder: And phone often does not happen

Anthony Master:

#3. The Solution I think would look something like this:
1. The pharmacy receives an Rx
2. The pharmacy checks local inventory and cannot meet the Rx drug/quant.
3. A web interface for the Pharmacy to send out a request to a central API to check for nearby availability
4. Central API sends queries out to (preset range/agreed upon parties/opted-in) Pharmacies to check for specific drug/quant.
5. Other Pharmacies receive query for drugs/quant either through interoperability standards like HL7/FHIR with the inventory system

6. Other Pharmacies respond with yes/no that they can meet the request.

7. After the allotted timeout or after all selected Pharmacies reply, the Central API sends ou the tallied reply back to the original requestor.

Summerpal Kahlon: What Catherine mentions at NCPDP may work. I don't need to know all drugs everywhere, I just need to know where to get the 1 drug my patient needs at the moment

Margaret Weiker: NCPDP has a task group: Pharmacy Product Locator Task Group whose purpose is to investigate creating a technical solution for pharmacies to query pharmacies, in a given geographical area, to locate pharmacy prescription products on behalf of the patient. Anybody can participate in a NCPDP Task

Group. Information on how to join a task group - https://standards.ncpdp.org/Standards/media/pdf/EmailToExistingTaskGroups.pdf

Alexis Snyder: Love that Anthony-also needed is sometimes need to change dose or med to get filled efficiently

Pooja Babbrah: I'm happy to help and I think we need to pull some folks from NCPDP as needed

Heidi Polek: How do you take into account in/out of network pharmacy for the patient. A pharmacy that has the med may actually be out of network for the patient which would cost the patient more out of pocket

Alexis Snyder: In coordination with provider that is

Jim Jirjis: I think we would need to understand the scope of what data and situations we are talking about. One thing is what is the source of truth for what the patient should die taking/receiving. Another is whether there is supply available for those items

Heidi Polek: and again, pharmacies don't want to give away script fills. with orders coming within 24 hrs, in most cases the patient will be satisfied

Pooja Babbrah: Thank you Margaret for sharing the link to the task group.

Summerpal Kahlon: Thinking about the context of a public health emergency, I think cost and network status is more of a payer/funding issue to address

Heidi Polek: Alexis Snyder-the Rxchange message can be used to communicate with a prescriber that the pharmacy would like to dispense a different product than the original one prescribed

Pooja Babbrah: @steven - agree. And the impact of Limited Distribution. this information is not always shared with providers. The script gets bounced around and delays the patient on getting on therapy

Anthony Master: @Heidi Polek, I don't think the solution needs to account for all of that. Just shows who has it available, not if they are in network or not. That would be an additional thing for the customer to resolve. Just get a list of who may have it, and let the customer contact that Pharmacy directly. It solves the need to call around and waste Pharmists and Tech time just to check inventory

Alexis Snyder: Yes Heidi but doesn’t happen currently

Heidi Polek: why try to build something new if there is already a solution? the best thing to do is work on ways to increase utilization of RxChange

Alexis Snyder: @Anthony-putting the patient/caergiver I the middle to solve when they cannot for many reasons is not an acceptable solution. Often requires new PA, new Script etc

Pooja Babbrah: Agree on increase utilization of RxChange. We are starting to see uptake. This could fall in the certification category

Anthony Master: @Alexis the common workflow at least in our area of the world, is the Pharmacy/PA putting the patient responsible for finding an alternative Pharmacy with supply on hand. Not referring to alternative fills, but just general unavailability in cases of drug shortages in local communities.

Steven Lane: Is there an opportunity to recommend the high priority content for health data exchange between pharmacists and other providers. While full USCDI exchange might be a long term goal, the PAMI data (problems, allergies, medications, immunizations) would seem most critical to informing the care process in pharmacies and the information transfer back to the remainder of the care team.

Pooja Babbrah: Question for ONC - I think RxChange is part of MU certification, but we could focus on certification of pharmacy systems. Something we should dig into a bit more

Steven Lane: We heard at our last meeting substantial concerns from individuals regarding the privacy risks related to allowing pharmacists and their staff access to too much EHI. Starting with PAMI exchange might mitigate these concerns.

Jim Jirjis: Without some level of certification for other entities than just EHR's it is like only one dance partner knowing the steps

Pooja Babbrah: +1 Jim

Pooja Babbrah: +1 Shelly's comments re: specialty

Heidi Polek: Happy to work with you on some ideas for RxChange @pooja

Steven Lane: @Jim - We could potentially link the data exchange requirements with ePrescribing. Is it even safe to send a prescription to a pharmacy that is not connected to the data exchange framework? If only interoperable pharmacists could receive eRx from certified EHRs this would drive their connectivity in short order.

Jim Jirjis: @Steven. I concur and propit that it is unsafe.

Donna Doneski: We in LTPAC strongly support the use of health IT standards. We would encourage focusing on the use of standards rather than perpetuating certification as currently constructed to ensure compliance with use of HITECH funding to sectors that did not receive such funds.

Heidi Polek: Will this spreadsheet be shared with the general public? It's hard to truly understand all the content at this very moment. I'd like time to dig in deeper

Steven Lane: Good point Jim - Pharmacy dispense data as a Syndromic Surveillance signal.

Mike Berry (ONC): @Heidi - The spreadsheet is a task force working document and is only shared online during public meetings.

Summerpal Kahlon: Agree with that comment, need to have a set of requirements/solution that is consistent across all agencies

Jim Jirjis: @Ike. Here here

Mike Berry (ONC): A recording to this meeting will be available shortly after the meeting at: https://www.healthit.gov/hitac/events/pharmacy-interoperability-and-emerging-therapeutics-task-force-2023-1

Afton Wagner: I can join you, Pooja!

Pooja Babbrah: Happy to lead a group on this

Heidi Polek: I can work with you Pooja

David Butler: I will be glad to join

Kim Boyd: We also have to be able to facilitate the communications back from the MD, etc. to the pharmacist on the actions they took based on the recommendations from the ecareplan

Kim Boyd: Happy to join this effort

Shelly Spiro-PHIT: @Pooja Shelly will join discussion on Pharmacist eCare Plan (PeCP)

Pooja Babbrah: Thanks Shelly

Heidi Polek: My company's software solutions can interact with IIS

Kim Boyd: As we think about certification of pharmacists systems, etc. I would encourage ONC to evaluate the challenges in interoperating between current EHRs and take those lessons learned to apply to pharmacist systems/PEHRs (Pharmacy EHRs)

Pooja Babbrah: I think it may be worth having some pharmacy management system vendors present as SMEs. I know we have a few folks on the task force itself, but may be worth having some presentations at one of our meetings so this group can better understand current functionality of these systems

Catherine Graeff: IIS I believe requires HL7 format fore reporting and pharmacies so not currently support. Most pharmacies use an intermediary to send data in the proper format to IIS.

Pooja Babbrah: +1 Kim Boyd

Shelly Spiro-PHIT: @CathyG IIS Health Level 7 (HL7) Implementation
https://www.cdc.gov/vaccines/programs/iis/technical-guidance/hl7.html

Afton Wagner: Challenges for pharmacies in using standards such as HL7 include getting the data formatted in these standards and getting/maintaining the mechanism for transmission

Steven Eichner: Catherine +1 on HL7 interfacing as the standard used by IIS. There is a specific implementation guide that provides constraints on message contents.

Steven Eichner: One of the potential certification options would be to certify the product on generating (and being able to receive) a properly-formatted HL7 message, such that an HL7 message generated by the system produces properly formatted data with the appropriate and accurate content.

David Butler: I'd like to offer the recommendation found at this link: https://1drv.ms/w/s!AtrqGFyBcSwhxLMH7Si4vYlUHQ8S9w?e=on0XQn. Sorry, but I can't seem to paste it in Chat.

Hans Buitendijk: @david: Can you paste it into the Google Spreadsheet?

Steven Lane: Sorry that I inadvertently sent my earlier chats to Hosts & Panelists. Can these be captured for the public record, or do I need to re-post them to Everyone to accomplish this?

Anthony Master: How has HL7 standards been out for decades and there is still discussion if it should be used or not. Hopefully we'll move to FHIR soon more widespread instead of v2/CCD.

Heidi Polek: I have to drop for a work call. I appreciate the work this group is doing, and look forward to helping where I can

Steven Lane: A key issue with Paxlovid prescriptions is potential interactions with other medications (e.g., statins, oral anticoagulants) that the patient may be taking. This is a great example of where pharmacists participating in test-to-treat protocols, or even simply dispensing in response to a received prescription, need to have access to patient health data, especially a complete and accurate medication list.

Kim Boyd: @Anthony Master - I would offer that without the requirement, via policy, to utilize any particular standard that it is then left to the industry and business to prioritize its use in alignment with their business goals, technology roadmap and more. If the ROI is not clearly present, many organizations, especially pharmacies who many are operating on shoe-string budgets (such as community pharmacies), will not prioritize using or updating to a new standard.

David Butler: @hans: Yes. Can you please provide me a reminder of where to find the spreadsheet link? I can't seem to find it in emails or on the website.

Tricia Lee Rolle: I will send it you to directly David

Kim Boyd: RxFill (NCPDP) utilization by the pharmacy and then reporting could help resolve this issue of understanding what was dispensed vs what was prescribed and claim submitted for.

Pamela Schweitzer: Dispense data is much better than claims data.

Pooja Babbrah: +1 Pam

David Butler: Some patients pay cash for their prescription and request via HIPAA that their prescription information not be shared with the insurer. This reduces data availability in claims.

Justin Neal: +1 David. Also some claims may be billed by the pharmacy thru the medical benefit vs prescription benefit at times.

Alexis Snyder: Plus 1 to Ike as mentioned previously patients/caregivers need to have control over what gets shared with whom and when

Donna Doneski: How does pharmacy coordinate this data with other providers? And how do State IISs/ Public Health agencies sync up eCR/ required reporting sync without added burden? There are multiple points where data could be generated on the same patient and it's unclear how data sharing alleviates burden across multiple providers.

Steven Lane: Do pharmacists engaging in onsite COVID-19 testing (e.g., in test to treat scenarios) have a requirement to do case reporting to public health? Have m/any set-up eCR connections?

David Butler: I agree with Steven regarding privacy. One potential answer to helping patients monitor their data accessibility would be for ONC (or an appropriate entity) to establish a national data warehouse that utilizes a relational database system to allow each patient to sign on and see all time-based, login-based accesses to their records within EHRs and other healthcare records. A well-designed interface will allow a patient to (at any time and as often as desired) provide or deny access to all healthcare participants (both individual and corporate).

Pooja Babbrah: Steven - can you confirm what is PAMI data?

Jim Jirjis: Do phamarcy information systems have the technical ability to do automated reporting (like eCR)?

Summerpal Kahlon: The problem everyone is describing here isn't jus a pharmacy problem - it's back to the nationwide interoperability problem

Jim Jirjis: @Mary Kay. Are you suggesting a national data repository (there are some big costs and issues associated with that also)

Summerpal Kahlon: Physicians can't readily access this information amongst each other either at this stage. Not a unique problem to pharmacy

Steven Lane: @ Jim - They should if the pharmacists are making diagnoses, especially reportable conditions, and especially if they are treating them themselves, so that the patient does not need to seek care from a physician who will do the reporting.

Shelly Spiro-PHIT: @Jim there may be pockets of areas (e.g. TX as stated by Ike) but not normally. There are issues with on-boarding pharmacies to submit data. due to the fact that CMS does not recognize pharmacy/pharmacist as a provider under the Social Security Act.

Jim Jirjis: Particularly ELR and Immunizations, but I could imagine Sureveillance also

Donna Doneski: @Shelly - It might be time to reconsider whether pharmacists SHOULD be providers under SSA.

Alexis Snyder: +1 to Steven

Kim Boyd: +1 to Shelly and Steven

Anne Burns to Everyone: Agree! There are active efforts underway in the pharmacy community to pass legislation in Congress to recognize pharmacists as providers.

Kim Boyd: The state policies are also all over the place with provider status

Kim Boyd: For pharmacist

Pooja Babbrah: +1 to Shelly and Steven (and Kim)!

Pooja Babbrah: Great discussion all! So many things to work on but it's great to see the focus on these topics

Shelly Spiro-PHIT: Thank you every one all your comments and recommendations!

Kim Boyd: Thanks TF and commenters!

QUESTIONS AND COMMENTS RECEIVED VIA EMAIL

No comments were received via email.

Resources

Pharmacy Interoperability and Emerging Therapeutics 2023 Webpage
Pharmacy Interoperability and Emerging Therapeutics 2023 – July 12, 2023 Meeting Webpage
HITAC Calendar Webpage

Adjournment

The meeting adjourned at 12:00 PM.